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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/630,923      | 07/31/2003  | Pierre Hoerner       | 045636-5070         | 7579             |

9629 7590 04/25/2005

MORGAN LEWIS & BOCKIUS LLP  
1111 PENNSYLVANIA AVENUE NW  
WASHINGTON, DC 20004

EXAMINER

RAYFORD, SANDRA M

ART UNIT PAPER NUMBER

1772

DATE MAILED: 04/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/630,923

Applicant(s)

HOERNER ET AL.

Examiner

Sandra M. Nolan-Rayford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 23-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 23-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claims***

1. Pursuant to the entry of any amendments in the response dated 18 January 2005 ("the last response") in reply to the office action dated 15 September 2004 ("the last office action"), claims 1-19 and 23-27 are pending.

### ***Summary of Base Claim***

2. Claim 1, the sole base claim, can be summarized as follows:

3. Claim 1 covers a multilayer elastomeric material comprising:

-two or more outermost elastomeric barrier layers L1 and L3, with breaking stresses of S1 and S2, thicknesses of T1 and T2, and elastic constants E1 and E3, respectively,

-one or more intermediate layers, L2, between L1 and L3 that consist of an elastomeric matrix comprising one or more dispersions of droplets containing an active substance, with L2 having a breaking stress S-2T, thickness T2 and an elastic constant E2,

wherein the mean diameter of the droplets is 10 um or more and the material satisfies the formulas Ia and Ib:

$$Ia \text{ is } (S-2T \times E2) < (S1 \times E1)$$

$$Ib \text{ is } (S-2T \times E2) < (S3 \times E3),$$

with all terms in the equations being defined earlier in the claim.

4. Apparently, the droplet-containing layer(s) have (breaking stress x elastic constant) ("SxE") values that exceed the SxE's for the outermost layers.

### ***Rejections Withdrawn***

5. The 35 USC 112 rejection of claims 1-19 and 23-27 set out in section 5 of the last office action has been withdrawn in view of the amendments to the claims in the last response.

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6. The 35 USC 112 rejection of claims 6-8 set out in section 6 of the last office action has been withdrawn in view of the amendments to the claims in the last response.

***Rejections Maintained***

7. The 35 USC 103 rejection of claims 1-12, 14-16, 19 and 23-27 as unpatentable over Applicants' admission in view of Crepeau et al (US 6,391,326), as explained in section 9 of the last office action, is maintained for reasons of record.

8. The 35 USC 103 rejection of claims 13 and 17-18 as unpatentable over Applicants' admission in view of Crepeau and Hoerner et al (US 6,020,070), as set forth in section 10 of the last office action, is maintained for reasons of record.

***Response to Arguments***

9. Applicant's arguments filed in the last response have been fully considered but they are not persuasive. They will be responded to in the order in which they were presented.

On pages 6-7 of the response, applicants have summarized the rejections made against the claims.

Since the 35 USC 112 rejections have been withdrawn, they will not be discussed here.

On page 7, in the last sentence, applicants argue that that—while they have acknowledged that the prior art describes multilayer films with droplets of active agents in intermediate layers—that acknowledgement does not mean that these admittedly old films have the high performance qualities observed in Applicants' materials. They go

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on, on page 8, to say that these qualities include the "double inequality" relationship set out in formulas 1a and 1b (paraphrased above) which lead to phenomena that the films "unexpectedly" release amounts of active agent from the intermediate layer that are 10 times less (in terms of active agent volume on a piercing object) and they "unexpectedly" expel the active agent 5 times slower (in terms of rate of expulsion from the intermediate layer), when compared to release values for films that do not have this "double inequality".

However, the discovery of an arithmetic relationship between the properties of the layers of a composite is not a proper basis for patentability. If applicants choose to recite the "unexpected" properties ascribed to their composites in language that describes the properties themselves, instead of arithmetic relationships discovered based on measurements of the properties and/or other properties of the layers in their composites, the claims would be re-considered in view of such recitations.

On page 9, applicants argue that such properties as resistance to piercing force and thickness affect the rupture of the layers for which these properties are evaluated.

However, a layer's resistance to piercing would be expected to be related to such factors as thickness, the amount of stress it can withstand before its surface breaks, etc.

On page 9, applicants argue that it has shown unexpected advantages over the prior art.

However, the properties demonstrated in volume and expulsion rate properties discussed are completely consistent with the behavior of films that are subjected to stress in the presence of articles that are designed to penetrate them.

On page 10, applicants argue that Hoerner does not teach or suggest the double inequality recited in their claims.

However, when, as here, the structure of the composites taught by the combined references suggests the structure recited in the claims, the arithmetic descriptors that may be applied to describe the properties of the composites' layers are deemed latent properties; they do not render the claims patentable. See MPEP 2145(II).

***Final Rejection***

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

11. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Citations as of Interest***

12. The Japanese abstracts are cited for teaching that arithmetic relationships can be derived for variables ascribed to layers in multilayer systems.

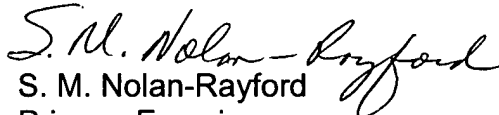
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**Conclusion**

Any inquiry concerning this communication should be addressed to Sandra M. Nolan-Rayford, at telephone number 571/272-1495. She can be reached Monday through Thursday, from 6:30 am to 4:00 pm, ET.

If attempts to reach the examiner are unsuccessful, contact her supervisor, Harold Pyon, at 571/272-1498.

The fax number for patent application documents is 703/872-9306.

  
S. M. Nolan-Rayford  
Primary Examiner  
Technology Center 1700

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